Illinois Health and Hospital Association

March 28, 2019

ILLINOIS HEALTH AND HOSPITAL ASSOCIATION
M E M O R A N D U M

TO: Deputy Governor Christian Mitchell
Illinois House Speaker Michael Madigan
Illinois House Republican Leader Jim Durkin
Illinois Senate President John Cullerton
Illinois Senate Republican Leader Bill Brady

Cc: Legislative Staff

FROM: A.J. Wilhelmi, President & CEO
David Gross, Senior Vice President, Government Relations

SUBJECT: **Potential Impact of Banning Ethylene Oxide (EtO) on Access to Healthcare**

On behalf of its over 200 hospital and nearly 50 health system members, the Illinois Health and Hospital Association (IHA) appreciates the opportunity to provide input on the work that the Administration and General Assembly are doing around the important issue of EtO. The hospital community recognizes that reasonable environmental oversight is necessary to protect the environment and the public from materials that may jeopardize health and safety. We rely on experts in environmental science to provide guidance and regulation to protect the public health. At the same time, patients' access to safe and effective health care will be affected if access to sterile medical supplies is disrupted. Thus, public policy must strike a careful balance between the appropriate regulation of EtO and patients' access to sterile medical supplies.

Banning Ethylene Oxide
Much of the discussion and legislative proposals set forth to date would completely phase out the use of EtO in Illinois over a defined period of time. We understand that there is significant concern about the health of communities where large EtO sterilization facilities are located. **However, there is serious concern that banning EtO will disrupt access to sterile medical supplies, and therefore, access to healthcare.** The following is the basis for our concerns:

Hospital Reliance on Illinois Based EtO Sterilizer
Medline is a key supplier of surgical and supply kits to many Illinois hospitals. If Medline's Lake County facility were to be impacted, there is significant concern regarding a potential disruption in access to medical and surgical supplies. Based on comments from Medline representatives, we understand that in addition to the Medline product, more than 20 medical device manufacturers utilize Medline's sterilization facility. Many of the devices that are sterilized at Medline's facility do not have access to backup sources to EtO sterilization. These devices will almost certainly be in shortage for many months if Medline's Lake County facility were to be impacted. **Nearly 80 percent of hospitals in Illinois utilize devices sterilized at Medline's Lake County facility.**[1]

[1] Based on statements from representatives of Medline.

1151 East Warrenville Rd.
P.O. Box 3015
Naperville, IL 60566
630.276.5400

700 South 2nd St.
Springfield, IL 62704
217.541.1150

400 North Capitol St. N.W.
Suite 585
Washington, DC 20001
202.624.7899

833 West Jackson Blvd.
Suite 610
Chicago, IL 60607
312.906.6150

www.team-iha.org

Hospitals Use of Pre-Sterilized Equipment and Supplies
For most surgeries and procedures, hospitals utilize pre-sterilized supply kits that include everything necessary for the procedure (e.g., bandages, gauze, gowns, drapes, surgical tubing and all other disposable materials used during surgery) as well as similar kits for labor and delivery. Many of these supply kits are customized based on the particular procedure or the requirements of the particular physician. Therefore, it would likely take hospitals several months to identify and switch to an alternative supplier, if available.

Concerns Raised by the U.S. Food and Drug Administration (FDA)
EtO is currently used to sterilize the supply and surgical kits discussed above. According to a March 26, 2019, Statement from the FDA, **"About half of all sterilized medical devices undergo sterilization using ethylene oxide."** While many sterilization methods are used (e.g., gamma radiation, e-beam, dry heat and steam sterilization), some sterilization methods are not compatible with some devices, components and materials.[2] The statement also recognizes the potential for a shortage of medical supplies: "[W]hile every effort is being taken to prevent a potential shortage, we're monitoring the situation closely and stand ready to act quickly with strategies intended to limit the impact of device supply interruptions on patients."

Finally, the FDA points out it will take time to develop new sterilization processes: "[A]s we continue to monitor any shortages associated with facility closings, we're also working with stakeholders … to identify innovative ways to sterilize medical devices that don't raise the same concerns as those identified at the Willowbrook facility. … We've already started exploring ways we can continue to ensure sterilization processes are safe and effective, and evolving with the current science. … We're seeking to not only limit the immediate impact of these facility closures, but also to identify new and improved methods for medical device sterilization."

For these reasons, there is significant concern that banning EtO will disrupt access to sterile medical supplies and healthcare for Illinois patients. IHA again appreciates the opportunity to provide input on this important issue. The use of EtO and its impact is very complex. The hospital community seeks to continue to work with you on this topic to ensure that environmental concerns are addressed while still allowing an avenue for hospitals to have access to appropriately sterilized medical products and equipment.

If you would like to discuss this issue further, please contact David Gross at 217-541-1161 or dgross@team-iha.org.

[2] US Food and Drug Administration (FDA), *Ethylene Oxide Sterilization for Medical Devices*